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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,166	11/12/2003	Lorin Olson	LFS-5001USA-CIP	7031

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EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,166	OLSON ET AL.	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-19,21,23-31,33-40 and 42-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-19, 21, 23-31, 33-40, and 42-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the amendment filed 12/17/2007.

2. Claims 1, 2, 4-19, 21, 23-31, 33-40, and 42-46 are currently pending.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 4-10, 15-19, 21, 23-31, 33-40, and 42-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Moerman (US 6,706,049). Regarding claims 1, 2, and 35, Moerman discloses a cap (Fig 1, element 10) for a dermal tissue lancing device including a housing (12) and a lancet (30) that is movable with respect to the housing (col 4, lines 15-19). The cap comprises a proximal end (32) for engaging with the housing (element 20; col 4, lines 49-52), a distal end (34) defined by deformable first and second portions (Fig 3A, elements 24 and 26) for engaging with dermal tissue, and an opening (18) defined by an edge of the first and second portions for a portion of the lancet to pass through (col 4, lines 46-48). When the cap contacts and is urged towards the dermal tissue, the first and second portions deform resiliently to reduce the size of the opening, engage the tissue, and approach theretogether to form a bulge in the tissue (Fig 4B; col 7, lines 5-16).

Regarding claims 4-5, Moerman discloses the first and second portions define a continuous circular ring for engaging and surrounding the tissue (Fig 3A).

Regarding claims 6-7, Moerman discloses the cap is at least partially formed of a resilient, deformable material (col 10, lines 52-55), including elastomeric materials, polymeric materials, polyurethane materials, or latex materials (col 10, line 56).

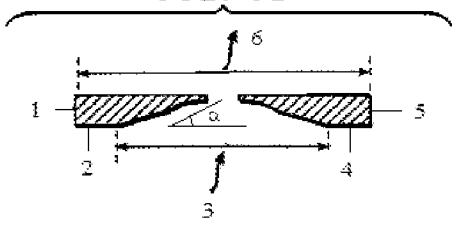
Regarding claims 8-9, Moerman discloses the cap is made of a material sufficiently transparent to distinguish a fluid sample to be withdrawn with the dermal tissue lancing device (col 4, line 62 - col 5, line 4). Alternatively, the cap may be formed of a non-blood colored material, such as white (col 5, lines 54-61).

Regarding claim 10, Moerman discloses the cap has graded resilience such that the distal end is more resilient than the proximal end. The proximal end comprises the connector (20) which is threaded to connect to the housing or is capable of being snap fit with the housing (col 4, ln 49-58), while the distal end is formed of a deformable, resilient, flexible material that may conform to the shape of the body region of the user (col 10, ln 52-55). Thus, it is inherent the proximal end must be more stiff than the distal end such that the proximal end does not deform when the cap body is connected to the housing.

Regarding claims 15-16, Moerman discloses the first and second portions are inwardly bendable (Fig 15), where the inwardly bendable portions contain skin-gripping teeth (col 11, lines 8-11).

Regarding claims 17-18, Moerman discloses the first and second portions have a six-sided cross-section as shown below in Figure 4C. Furthermore, the cross-section includes an internal angle that determines a compressed position of the cap during use, as represented by α below.

FIG. 4C



Regarding claim 19, Moerman discloses the cap is capable of being stackable with other identical caps, since the cap is preferably removably and replaceably connected to the housing (col 12, lines 5-6).

Regarding claim 21, Moerman discloses the cap is capable of applying a pre-lance pressure to maintain the bulge prior to lancing by the device and of applying a post-lance pressure to further maintain the bulge after lancing by the device (col 7, lines 5-16).

Regarding claims 23 and 36, Moerman discloses the cap further comprises a cap body (Fig 7, element 14) and a retainer (60). The cap body has a proximal end (66) for engaging with the retainer and a distal end (16) for engaging with dermal tissue. The retainer has a proximal end (62) for engaging with the housing and a distal end (68) for engaging with the cap body. The distal end of the cap body includes the resiliently deformable first and second (24 and 26) portions, which reduce the opening of the cap body when engaging dermal tissue.

Regarding claims 24 and 27, Moerman discloses the retainer includes a stop (64A) to prevent the proximal end of the cap body from deforming outwardly in a plane containing the opening and to prevent the cap body from deforming in a direction perpendicular to the plane containing the opening.

Regarding claims 25-26 and 31, Moerman discloses the proximal end of the cap body may freely rest within the retainer or may alternatively be fixedly mounted to the retainer or formed integrally with the (col 7, lines 50-54).

Regarding claims 28-30, Moerman discloses a pivot is formed on the cap body (16) and within the retainer such that when the cap is urged towards the tissue, the cap body pivots to fold in on itself within the retainer to reduce the size of the opening (Fig 15). Furthermore, Moerman discloses a weak region is included on the cap body to allow it to fold in on itself (Fig 15).

Regarding claim 33, Moerman discloses the retainer has an inwardly facing recess (Fig 6) for receiving the cap body and an inwardly protruding rim (Figs 7-8, element 70) to cooperate with the outside surface of the cap body (14).

Regarding claim 34, Moerman discloses the cap body is flexible (col 10, lines 52-55).

Regarding claims 37-39, Moerman further discloses the cap for a dermal tissue lancing device may also be coupled with a metering device to extract a fluid sample and measure an analyte within the sample (col 4, lines 40-42). Additionally, Moerman discloses a fluid collection device, such as a test strip, may be placed adjacent the lancing position after lancing to collect and measure the fluid sample (col 1, lines 36-37).

Regarding claims 40 and 42-46, Moerman further discloses a method for collecting a fluid sample using the device as previously described. The method comprises contacting the cap with the dermal tissue such that at least the first and

second portions engage the dermal tissue, urging the cap towards the dermal tissue such that at least the first and second portions deform resiliently and approach theretogether to close the opening and create a bulge in the tissue, applying a pre-lance pressure to maintain the bulge, lancing the bulge to create a puncture, applying a post-lance pressure for about five seconds, and collecting a fluid sample, such as a blood sample, from the puncture (col 7, lines 1-16; col 10, line 34 - col 11, line 2).

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman (US 6,706,049), as applied to claim 1 above, in view of Patil (US 6,238,575). Moerman discloses the invention substantially as claimed including a dermal tissue lancing device comprising a housing, a lancet, and a deformable cap. However, Moerman does not disclose the device comprises antimicrobial material. Patil discloses a fluid system device comprising a non-leaching antimicrobial agent that inhibits the growth of microorganisms incorporated into the device, such as 2,4,4-trichloro-2-hydroxy-diphenol (col 3, lines 25-28 and col 4, lines 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moerman such that the cap is at least partially formed of an antimicrobial material or such that the cap contains an antimicrobial coating, wherein the antimicrobial material may be a trichlorophenol compound such as = 2,4,4-trichloro-

2-hydroxy-diphenol. Thus, when the device comes into contact with body fluids, the growth of microorganisms will be inhibited, allowing the device to be sanitary and safe with a decreased possibility of contaminating the patient with bacteria.

Response to Arguments

7. Applicant's arguments filed 12/17/2007 have been fully considered but they are not persuasive. Applicant argues Moerman does not teach the "contact ring" is constructed from a resiliently deformable material. The Examiner respectfully traverses the Applicant's remarks. The specification of Moerman specifically states "the contact ring portion of the cap is comprised of a flexible material" in column 2, lines 36-37. Furthermore, since the flexible surface conforms to the surface of the skin, it is inherent the material is at least minimally resiliently deformable.

8. Furthermore, Applicant argues Moerman does not teach the opening through which the lancet passes is reduced in size when the cap contacts and is urged towards the dermal tissue. The Examiner respectfully traverses the Applicant's remarks. It is inherent that when the cap contacts and is urged towards, or pressed against, the dermal tissue, there will be at least some deformation in the flexible surface portions, or first and second portions, of the cap towards the housing. Thus, the length, or depth, of the opening is reduced in size at least minimally.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
March 14, 2008

/K. M. D./
Examiner, Art Unit 3734